PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 145065-9 DK	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/IL 03/00427	International filing date *(day/month/year)* 22.05.2003	Priority date *(day/month/year)* 23.05.2002
International Patent Classification (IPC) or both national classification and IPC A61F2/06		
Applicant ALLIUM INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☒ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
16.12.2003	16.08.2004
Name and mailing address of the international preliminary examining authority: European Patent Office - Gitschiner Str. 103 D-10958 Berlin Tel. +49 30 25901 - 0 Fax: +49 30 25901 - 840	Authorized Officer Amaro, H Telephone No. +49 30 25901-562

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IL 03/00427

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-8 as originally filed

Claims, Numbers

1-19 received on 02.06.2004 with letter of 31.05.2004

Drawings, Sheets

1/7-7/7 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 18

   because:

   ☒ the said international application, or the said claims Nos. 18 relate to the following subject matter which does not require an international preliminary examination (specify):

   see separate sheet

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees, the applicant has:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

☒ complied with.

☐ not complied with for the following reasons:

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☒ all parts.

☐ the parts relating to claims Nos. .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-17,19
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-17,19
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-17,19
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item III
Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claim 18 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to novelty, inventive step and industrial applicability (Article 34(4)(a)(I) PCT).

Re Item V
Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1:US 2002/040236 A1 (MARONEY CHARLES T ET AL) 4 April 2002 (2002-04-04)
D2:EP-A-1 110 561 (ETHICON INC) 27 June 2001 (2001-06-27)

D1 discloses a foldable stent comprising a hollow portion which has a generally circular cross-section when expanded. The stent's structure is made of a helically placed undulated wire. In the retracted position, the stent is constrained by a detachable wire that passes through loops associated with the helices as they wind about the stent, that is, the wire connects adjacent segments of the stent's structure helices.

D2 discloses a stent comprising a hollow portion defined by a helical structure having a plurality of coils made from a wound fibre. The adjacent coils of the helical structure may have a certain pitch between them or by me joined along their margins.

Nothing in D1 suggests that the material from which the filament of the detachable wire is made from a polymeric material. With relation with D2, nothing is suggested that the adjacent helical coils are to be, by any means, separated, that is, the coils are not detachable.

Therefore, the claimed invention is considered new and inventive.

CLAIMS:

1. A medical device having at least a hollow portion, the hollow portion being formed from a fashioned filament and having a detachable seam between at least one pair of adjacent segments of the fashioned filament, wherein the seam is formed by a polymeric material joining adjacent segments in the fashioned filament.

2. The medical device according to Claim 1 wherein a groove extends along a first edge of the filament and a ridge extends along a second edge of the filament, the seam being formed by snapping the ridge in a first segment of the filament into the groove in an adjacent segment of the fashioned filament.

3. The medical device according to any one of Claims 1 to 2 having a hook at end of the filament.

4. The medical device according to Claim 1 having a magnetizible portion at an end of the filament.

5. The medical device according to claim 1 being a stent, a catheter or an artificial blood vessel valve.

6. The medical device according to any one of the previous claims wherein the hollow portion has a circular, triangular or hourglass cross-section.

7. The medical device according to any one of the previous claims in which the hollow portion is bifurcated.

8. The medical device according to Claim 1 wherein the coating is perforated in the seams.

9. The medical device according to Claim 1 wherein the seam is formed by cutting the polymeric material and applying an outer polymeric coat to the device.

10. The medical device according to Claim 1 wherein the coating has a thickness in a portion of the seams that is less than the thickness adjacent to the filament.

11. The medical device according to Claim 1 wherein the filament has bends along its length.

12. A system comprising:

(a) A medical device formed from a fashioned filament and having a detachable seam between at least one pair of adjacent segments of the fashioned filament, the seam being formed by a polymeric material joining adjacent segments in the fashioned filament.

(b) A retrieving device having a grasping device configured to grasp an end of the filament.

13. The system according to Claim 12 wherein the medical device has a magnetizable portion at the end of the filament and the grasping device includes a magnetizable portion.

14. The system according to Claim 12 wherein the medical device has a hook at the end of the filament and the grasping device includes a hook.

15. The system according to Claim 12 wherein the grasping device includes a spring biased clamp configured to grasp the end of the filament.

16. The system according to any one of Claims 12 to 15 wherein the hollow portion has a circular or triangular cross-section.

17. The system according to any one of the Claims 12 to 15 wherein the hollow portion is bifurcated.

18. A method for removing a hollow portion of a medical device from a body, the hollow portion being formed from a fashioned filament and having a detachable seam being adjacent segments of the fashioned filament, the seam being formed by a polymeric material joining adjacent segments in the fashioned filament, comprising:

(a) grasping an end of the filament;

(b) pulling the end of the filament so as to detach the seam between adjacent segments of the fashioned filament.

19. A method for forming a hollow portion of a medical device, the hollow portion having a shape comprising the method:

(a) forming a filament into the shape of the device;

(b) forming a detachable seam between at least one pair of adjacent segments of the fashioned filament, the seam being formed by a polymeric material joining adjacent segments in the fashioned filament.